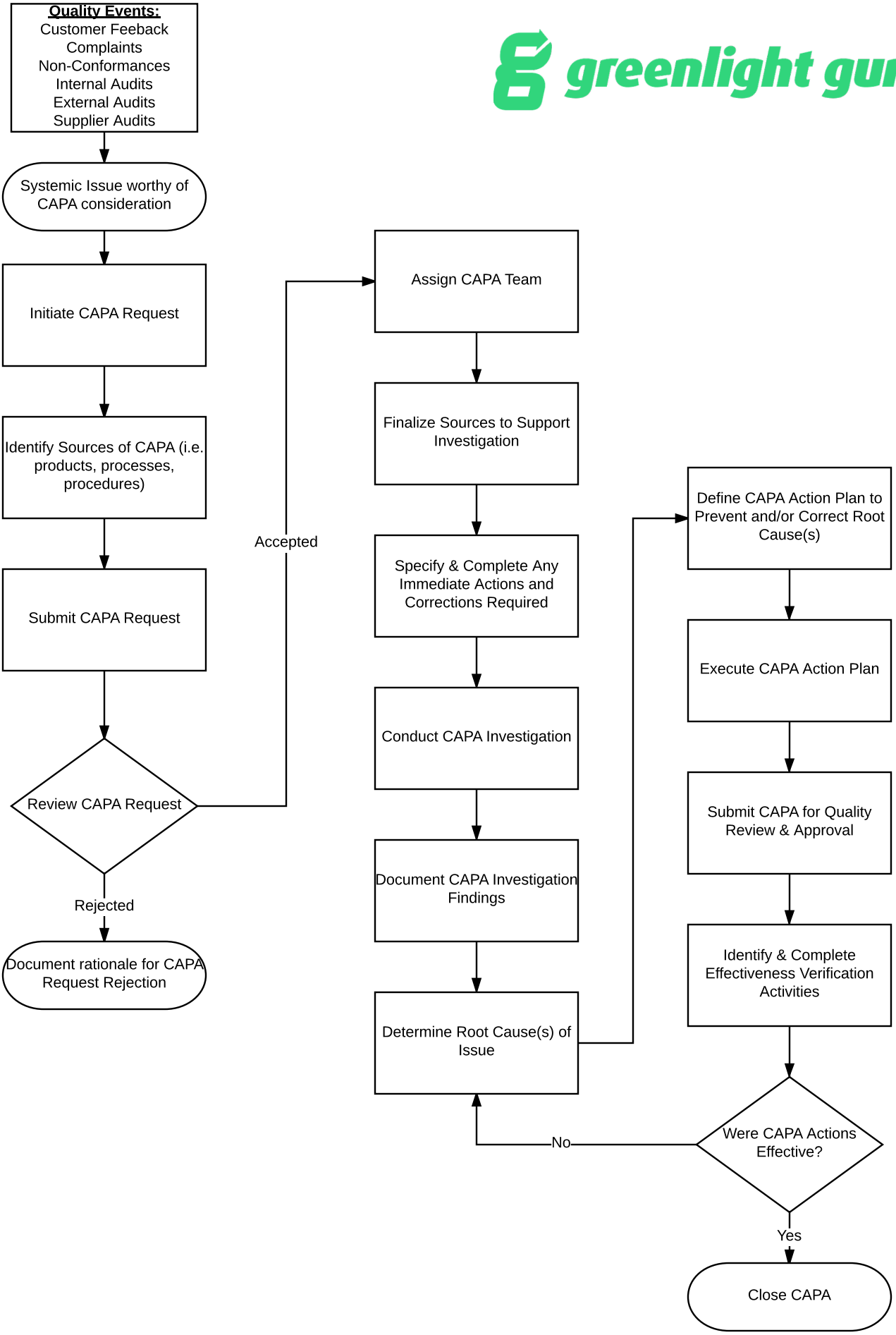
Quality Events:
Customer Feeback
Complaints
Non-Conformances
Internal Audits
External Audits
Supplier Audits
Systemic Issue worthy of CAPA consideration
Initiate CAPA Request
Identify Sources of CAPA (i.e. products, processes, procedures)
Submit CAPA Request
Review CAPA Request
Accepted
Rejected
Document rationale for CAPA Request Rejection
Assign CAPA Team
Finalize Sources to Support Investigation
Specify & Complete Any Immediate Actions and Corrections Required
Conduct CAPA Investigation
Document CAPA Investigation Findings
Determine Root Cause(s) of Issue
Define CAPA Action Plan to Prevent and/or Correct Root Cause(s)
Execute CAPA Action Plan
Submit CAPA for Quality Review & Approval
Identify & Complete Effectiveness Verification Activities
Were CAPA Actions Effective?
No
Yes
Close CAPA